K970718

MAY 27 1997

510(k) Summary

Quantikine™ IVD™ sTfR ELISA kit

Date of Summary:	February 14, 1997
Company Name:	R&D Systems, Inc. 614 McKinley Place N.E. Minneapolis, MN 55413
Contact name:	Kenneth T. Edds, Ph.D. 612-379-2956, FAX 612-379-6580
Classification name:	sTfR immunological test system
Product name:	Quantikine IVD sTfR immunoassay
Device Class:	Class II

Device to which substantial equivalence is claimed:
Sanofi Diagnostics ferritin assay, Chaska, MN, K926221

The product is a microtiter-plate-based sandwich enzyme immunoassay for soluble transferrin receptor.

The Quantikine™ IVD™ sTFR Enzyme linked immunosorbent assay is intended for the measurement of sTfR concentration in human serum or plasma as an aid in the diagnosis of iron deficiency anemia, especially the differential diagnosis of iron deficiency anemia and anemia of chronic disease.

R&D Systems' Quantikine IVD sTfR ELISA kit has an intended use that is similar to the predicate device. The technologies of the two devices are similar in that both are immunoassays involving the solid phase binding of an antibody-analyte-antibody* complex. They differ in the "reporter" moiety (*) attached to the complex. R&D System's assay is based on a colorimetric reaction and Sanofi's is chemiluminescent.

Testing of performance characteristics centered on the attributes of precision, linearity, specificity, sensitivity and stability. The assay is run at room temperature on the bench top.

Expiration dating for the kit has been established at 13 weeks when stored at 2-8°C and handled according to instructions for use. Opened or diluted reagents are good for up to 4 weeks when stored at 2-8°C provided that this is within the expiration date. The controls provided with the kit are lyophilized; once they are reconstituted they are stable for a minimum of 4 weeks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 27 1997

Kenneth T. Edds, Ph.D.
Regulatory Affairs
R&D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, Minnesota 55413

Re: K970718
Trade Name: Quantikine IVD sTfR Immunoassay
Regulatory Class: II
Product Code: JNM
Dated: February 26, 1997
Received: February 26, 1997

Dear Dr. Edds:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K970718

510(k) Number:

Device Name: The Quantikine™ IVD™ sTFR Enzyme linked immunosorbent assay

Indications for Use: The Quantikine™ IVD™ sTFR Enzyme linked immunosorbent assay is intended for the measurement of sTfR concentration in human serum or plasma as an aid in the diagnosis of iron deficiency anemia, especially the differential diagnosis of iron deficiency anemia and anemia of chronic disease.

Peter E. Maheri

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number _____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-CounterUse _____

(Optional Format 1-2-96)

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